

Remarks

The following remarks are provided in further support of the Claims.

Rejections

## Rejection Under 35 U.S.C. §102

Claims 1-11 are rejected under 35 U.S.C. §102(a) as being anticipated by Waggoner et al. ("Self-assembled columns..." in JACS 123 (3) 496-7 (2001).

Claims 1, 3-7, 9 and 11 are rejected under 35 U.S.C. §102(e) as being anticipated by Safinya et al. (US 6,358,523).

Claims 1-7, 9 and 11 are rejected under 35 U.S.C. §102(e) as being anticipated by Firestone et al. (US 6,537,575).

I. DISCUSSION - 35 USC §102(a) (Waggoner et al) Claims 1-11

Applicants herewith submit a declaration under 37 CFR §1.132 showing that, to the extent the disclosure in the paper of Waggoner et al. is a disclosure of the present invention claimed in the above-identified patent application, the co-author P. Kotula of the paper was working under direction of the one or more of the inventors of the Applicants' invention. The declaration establishes "that the article is describing applicant's own work" as required by MPEP 2132.01. The declaration is also provided by all of the inventors. Therefore, the cited reference is a publication of Applicants' own invention published less than one year prior to the filing date of the instant Specification and can thereby be removed as a reference according to MPEP 716.10 for rejection of claims 1-11.

II. DISCUSSION (Rejection Under 35 USC 102(e), Safinya et al., '523

Safinya et al. teach charged multilamellar macromolecule-lipid complex comprising lipid layers interspersed with macromolecules (such as DNA). As shown in FIGs. 3 and 5A of Safinya et al., lipid bilayers are interspersed with macromolecules such as DNA molecules. The lipid bilayer material extends two dimensionally (e.g., laterally) without any set boundaries, with the lipid bilayer

molecules extending laterally as well as vertically. Moreover, FIGs. 3 and 5A illustrate the lack of definitive boundaries by showing the lipid bilayer structure as a rectangular stack of material. These structures are microns wide (see FIGs. 3A and 5A) due to the lateral extent of the structure.

In the present invention, lipid bilayer materials self-assemble by stacking or layering themselves one upon another in a stacked, columnar structure (see Specification page 5, lines 12-22). The structure is a rod-like shaped structure (see Specification, page 3, lines 20-25). The maximum diameter of the columnar structure, and therefore of the discrete lipids, is 900 Angstroms (see Specification, page 7, lines 15-17). Therefore, the present invention differs from Safinya et al. in that (1) the lipid bilayer materials layer themselves upon one another where Safinya et al. lipid bilayer materials are two-dimensional structures where the molecules adhere to each other both laterally as well as vertically, with a mass of molecules forming layers with macromolecules interdispersed between the layers and (2) the lipid bilayer materials stack in a columnar rod-like structure with a maximum diameter of 900 Angstroms where the Safinya et al. lipid bilayer materials form a layer of undefined dimensions that extend laterally without a priori bounds to give a multi-micron dimensioned structure.

Therefore, Safinya et al. does not provide the elements of a plurality of lipid bilayer molecules, each lipid bilayer molecule layered upon another lipid bilayer molecule, in a stacked columnar rod-like shaped structure of less than a maximum of 900 Angstroms in diameter, as specified in claims 1, 3-7, 9 and 11 of the present invention.

### III. DISCUSSION (Rejection Under 35 USC 102(e), Firestone et al., '575

Firestone et al. teach a mixture which is a combination of a lipid, a polymer-grafted phospholipid and a surfactant. The mixture is a gel at certain temperatures and a liquid at other temperature intervals. As depicted in FIG. 3 of Firestone et al., the mixture self-assembles in a micellar arrangement with the lipids, phospholipids and surfactants oriented in a circular fashion. In particular, the lipid materials orient

with one end of the lipid molecules along the circular periphery and the other end oriented toward the center of the micelle. The micelles organize into a roughly rod-like or cylindrical structure. The micelles do not layer upon one another to form a rod-like structure. Firestone et al. teach a lattice spacing of the liquid phase of several hundred angstroms (e.g., 345 angstroms, Col. 7, line 54) but the cylindrical structure comprising the lattice elements are not lipid bilayer materials layered one upon another, as taught by the present invention and specified in claim 1 of the present invention. As described above, the cylindrical structures are mixtures of components where the lipid bilayer materials do not stack one upon one another but are oriented in a self-assembled fashion within micelle-like structures in a circular arrangement. In the present invention, lipid bilayer materials self-assemble by stacking themselves one upon another in a stacked, columnar structure.

Therefore, Firestone et al. does not provide the elements of a plurality of lipid bilayer molecules, each lipid bilayer molecule layered upon another lipid bilayer molecule, in a stacked columnar rod-like shaped structure of less than a maximum of 900 Angstroms in diameter, as specified in claims 1-7, 9 and 11.

#### CONCLUSION

Applicants have responded to each and every rejection raised by the Office and, in concurrence with the Office, consider that claims 1-11 are now in condition for allowance. Applicants request expeditious processing to issuance.

Respectfully submitted,



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